

FORM PTO-1390 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE  
REV. 2/01T

**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371**

CUSTOMER NO. 22,852  
ATTORNEY'S DOCKET NUMBER

04208.0210

U.S. APPLICATION NO.  
(If known, see 37CFR1.5)

**10/517381**

INTERNATIONAL APPLICATION NO.

PCT/JP03/07497

INTERNATIONAL FILING DATE

June 12, 2003

PRIORITY DATE CLAIMED

June 12, 2002

TITLE OF INVENTION

MEDICINE TRIAL PRODUCTION SUPPORTING SYSTEM

APPLICANT(S) FOR DO/EO/US


Nobuya KANEKO and Shunichi GOMI

Applicant(s) herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☒ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c)(2)).
  - a. ☐ is attached hereto (required only if not communicated by the International Bureau.
  - b. ☒ has been communicated by the International Bureau.
  - c. ☐ is not required, as the application was filed with the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371 (c)(2)).
  - a. ☒ is attached hereto.
  - b. ☐ has been previously submitted under 35 U.S.C. 154 (d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3)).
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☒ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☐ Information Disclosure Statement under 37 CFR 1.97 and 1.98
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A FIRST preliminary amendment.
14. ☐ A SECOND or SUBSEQUENT preliminary amendment.
15. ☐ A Substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821-1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154 (d)(4).
19. ☐ A second copy of the English language translation of the international application 35 U.S.C. 154 (d)(4).
20. ☒ Other items or information:
  - a. ☒ Copy of cover page of International Publication No. WO 03/107236 A1
  - b. ☒ Verification of Translation - 1 Sheet
  - c. ☒ Request for Substitution of Replacement Sheets

U.S. APPLICATION NO. (If known, see 37CFR 1.5) <b>10/517381</b>		INTERNATIONAL APPLICATION NO. PCT/JP03/07497		ATTORNEY'S DOCKET NUMBER 04208.0210	
21. <input checked="" type="checkbox"/> The following fees are submitted:				CALCULATIONS PTO USE ONLY	
BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):				\$300.00	
National Stage Search Fee.....				\$500.00	
National Stage Examination Fee.....				\$200.00	
ENTER APPROPRIATE BASIC FEE AMOUNT =				\$1000.00	
Surcharge of \$130.00 for furnishing the oath or declaration later than months from the earliest claimed priority date (37 CFR 1.492 (e)).				<input type="checkbox"/> 20 <input type="checkbox"/> 30	\$
CLAIMS	NUMBER FILED		NUMBER EXTRA	RATE	
Total Claims	1	- 20 =		x \$50.00	\$
Independent Claims	1	- 3 =		x \$200.00	\$
MULTIPLE DEPENDENT CLAIM(S) (if applicable)				+\$360.00	\$
TOTAL OF THE ABOVE CALCULATIONS =				\$1000.00	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				\$	
SUBTOTAL =				\$1000.00	
Processing fee of \$130.00 for furnishing the English translation later than months from the earliest priority date (37 CFR 1.492(f)).				<input type="checkbox"/> 20 <input type="checkbox"/> 30	\$
TOTAL NATIONAL FEE =				\$1000.00	
Fee for recording the enclosed assignment (37 CFR 1.21 (h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property.				+	\$
TOTAL FEES ENCLOSED =				\$1000.00	
				Amount to be refunded:	\$
				charged:	\$
a. <input checked="" type="checkbox"/> A check in the amount of \$ <u>1000.00</u> to cover the above fees is enclosed. b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>06-0916</u> . A duplicate copy of this sheet is enclosed. d. <input type="checkbox"/> Fees are to be charged to a credit card. <b>WARNING: Information on this form may become public. Credit card  information should not be included on this form. Provide credit card information and authorization on PTO-2038.</b>					
NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.					
SEND ALL CORRESPONDENCE TO: Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. 1300 I Street, N.W. Washington, D.C. 20005-3315					
DATED: December 10, 2004				 SIGNATURE Ernest F. Chapman Reg. No. 25,961 NAME/REGISTRATION NO.	

10/517381

DT03 Rec'd PCT/PTU 10 DEC 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re International Application of

Nobuya KANEKO et al.

International Application No.: PCT/JP03/07497

International filing date: June 12, 2003

For: MEDICINE TRIAL PRODUCTION SUPPORTING SYSTEM

VERIFICATION OF TRANSLATION

Honorable Commissioner of Patent and Trademark  
Washington, D.C. 20231

Sir:

Tomoo IWATA residing at c/o TANI & ABE, No. 6-20, Akasaka 2-chome,  
Minato-ku, Tokyo 107-0052, Japan, declares:

(1) that he knows well both the Japanese and English  
languages;

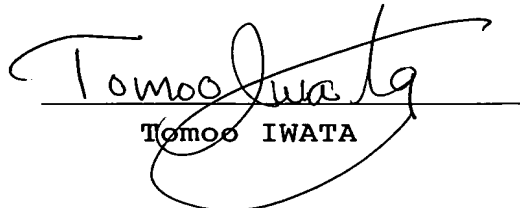
(2) that he translated the claims of the  
above-identified International Application from Japanese to  
English;

(3) that the attached English translation is a true  
and correct translation of the claims, specification and  
drawings of the above-identified International Application  
to the best of his knowledge and belief; and

(4) that all statements made of his own knowledge  
are true and that all statements made on information and belief  
are believed to be true, and further that these statements  
are made with the knowledge that willful false statements and  
the like are punishable by fine or imprisonment, or both, under  
18 USC 1001, and that such false statements may jeopardize  
the validity of the application or any patent issuing thereon.

December 6, 2004

Date

  
Tomoo IWATA

PCT/JP03/07497  
Nobuya KANEKO et al.  
Attorney Docket No. 04208.0210

**TRANSLATION OF THE ANNEXES TO THE  
PRELIMINARY EXAMINATION REPORT  
(ARTICLE 34 AMENDMENTS)**

**Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450**

Sir:


**REQUEST FOR SUBSTITUTION OF REPLACEMENT SHEETS**

Please substitute the attached replacement page 29 of the translation of the Article 34 Amendments for page 29 of the enclosed translation of the as-filed PCT application. Also, please substitute the attached replacement pages 1-4 of the translation of the claims of the Article 34 Amendments for pages 39-41 of the claims in the enclosed translation of the as-filed PCT Application. It is respectfully requested that the replacement page 29, and the claims on replacement pages 1-4 be examined during examination of the patent application. Claim 6 is currently pending.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: December 10, 2004

By:   
Ernest F. Chapman  
Reg. No. 25,961

EFC//FPD/gah